

REMARKS

Summary of Changes Made

The application was filed with 11 claims. In a preliminary amendment filed together with the application, new claims 12-17 were added. Presently, claims 9-11 have been canceled and all remaining claims, 1-8 and 12-17 have been amended. New claims 18-21 have been added. Claim 1 has been amended to include the limitation that the iron-carbohydrate complex has an average molecular weight of 80,000 to 400,000. Claims 1-8 and 12-17 have been amended for clarity and to put the claims into a style more typically used in U.S. patent practice. Several instances of "maltodextrin," (introduced in the preliminary amendment) including in claim 5, as pointed out by the Examiner, have been amended for proper spelling. Claim 5 has also been amended to recite that the reaction of oxidized maltodextrin and iron (III) salt is carried out at a pH of 2 or less, replacing the language "at a pH value so low that no hydrolysis of the iron (III) salt occurs." New claims 18 and 19 recite molecular weight limitations on the iron carbohydrate complexes of claim 1, while claims 20 and 21 recite reaction temperatures at which the reaction of claim 2 is carried out. A certified translation of the priority document is enclosed herewith to overcome a cited prior art reference. The specification has been amended to properly set forth the priority document and chain of parentage of the instant application. A terminal Disclaimer is filed herewith to overcome cited copending Application Serial Number 11/815,568. Accordingly, claims 1-8 and 12-21 (18 claims) remain pending in the application. No new matter is added by this amendment.

Claim Rejections - 35 U.S.C. §101

Claims 9-10 are rejected under 35 U.S.C. 101 as failing to set forth process steps in a process claim. The Examiner notes that "use" claims do not belong to a statutorily recognized category of invention, i.e., they lack utility.

The Examiner will note that claims 9 and 10 have been canceled, thus rendering their rejection moot.

Claim Rejections - 35 U.S.C. §112, 2nd Paragraph

Claims 9-10 are rejected under 35 U.S.C. §112, 2nd Paragraph as failing to set forth process steps in a process claim. The Examiner contends that notes that “use” claims without process steps rendered the claims indefinite. There are no active steps recited in the claims.

The Examiner will note that claims 9 and 10 have been canceled, thus rendering their rejection moot.

Claim Rejections - 35 U.S.C. §102(b) - (HCAPLUS Abstract 1960:117732)

Claims 1, 7, 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by HCAPLUS Abstract 1960:117732 (“HCAPLUS 1”). HCAPLUS 1 explicitly discloses ferric D-glucuronate. A solution obtained from an ion exchange column is concentrated and sterilized and used directly for injection for treating anemia.

The Examiner contends that the instant claims require a water soluble iron carbohydrate complex “obtainable” from an aqueous Fe (III) salt and an aqueous solution of the oxidation product of maltodextrin of various DE values. Because the Examiner contends that claim 1 does not specify all the necessary oxidation conditions and what is meant by “oxidation product,” he takes the position that the prior art ferric D-glucuronate is obtainable by oxidizing a maltodextrin of any DE value and reacting the oxidized product with a ferric salt. The Examiner cites U.S. Patent 5,831,043 as evidence that glucuronic acid is one potential oxidation product of maltodextrin, and concludes that the claims are anticipated.

The Examiner will note that claim 11 has been canceled, thus rendering the rejection moot. With respect to claims 1, 7, and 8, the Examiner will note that claim 1 has been amended to include the limitation that the iron carbohydrate complex has a weight average molecular weight (Mw) of 80,000 to 400,000. HCAPLUS 1 fails to disclose this limitation. Applicants thus respectfully submit that claims 1, 7, and 8 are novel over HCAPLUS1.

New Claims

New claims 18-21 have been added. Claims 18 and 19 relate to the molecular weights of the iron carbohydrate complexes of claim 1. Their subject matter is found in the specification at page 6, lines 16-25. Claims 20 and 21 relate to the reaction temperatures at which the reaction of claim 2 is carried out. Their subject matter is found in the specification at page 5, lines 18-24.

Applicants submit that new claims 18-21 are novel over HCAPLUS 1 because that reference fails to disclose the limitations of the newly added claims. Applicants respectfully request the entry of new claims 18-21 and notice of the patentability of said new claims.

Claim Rejections - 35 U.S.C. §103(a) - (HCAPLUS Abstract 2003:135397/Thaburet/Dokic)

Claims 1-8 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over HCAPLUS Abstract 2003:135397 ("HCAPLUS 2") in view of the acknowledged prior art, Thaburet et al., ("Thaburet") and Dokic et al ("Dokic"). HCAPLUS 2 discloses a method of making iron dextran as an iron supplement. The method involves adding a sodium hypochlorite solution to a solution of dextran and oxidizing at 20-25°C for at least 12 hours; adjusting a ferric chloride solution to pH 1.5-2 and reacting it with the oxidized dextran at 30-35°C for 1-1.5 hours; and neutralizing with a NaOH solution to pH 7-7.5.

The Examiner contends that Applicants admit that the following are known: use of iron carbohydrate complexes for prophylaxis of iron deficiency anemia; parenteral application of iron dextran complexes and complexes based on pullulans; oral application of iron carbohydrate complexes. Thaburet discloses oxidation of maltodextrin with TEMPO-NaBr-NaClO oxidizing system at a pH of 9.5. Dokic is cited to show that maltodextrins have a DE value 2-20 and are widely useful, which the Examiner contends is known in the art.

The Examiner admits that the prior art fails to expressly disclose Applicants' process of oxidizing maltodextrin and combining with an iron (III) salt to produce a water soluble iron carbohydrate complex. However, the Examiner contends that Applicants admit that iron carbohydrate complexes of many different types are known for providing physiological iron to subjects in need thereof.

The Examiner will note that a certified translation of the priority document (DE 10249552.1, filed October 23, 2002) is enclosed herewith. (A certified copy of the priority document itself already forms part of the record hereof, as acknowledged by the Examiner). A statement that the translation is an accurate translation of the priority document, signed by the translator, is included. The translation of the priority document shows that it is substantially the same as the present application except for some stylistic translation differences. As admitted by the Examiner, the earliest effective priority date of the instant application predates the publication date of HCAPLUS 2, and the provision of a certified translation of the priority

document perfects the claim of priority. It is thus believed that all rejections based on HCAPLUS 2 are moot as this document is no longer available as prior art with respect to the instant application.

In accordance with Examiner's proposal in the outstanding Office Action, Applicants respectfully request that Examiner provide an English translation of the subject matter of HCAPLUS1, i.e., Chinese Patent Application Publication CN 1353194.

Claim Rejections – Non Statutory Obviousness-Type Double Patenting

Claims 1-8 and 11-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 16 and 26-27 of copending Application No. 11/815,568 in view of HCAPLUS 2 and the acknowledged prior art, Thaburet and Dokic. The Examiner contends that Claim 26 of the copending application sets forth a process of making an iron (III) maltodextrin complex comprising contacting maltodextrin having a DE of 5-37 with an aqueous hypochlorite solution having a pH of greater than 7 to form a reaction mixture and contacting the mixture with an aqueous iron (III) salt solution. Claims 13 and 16 of the copending application set forth a medicament comprising a complex of an oxidation product of at least one maltodextrin with iron (III) in various medication forms. The discussion of the secondary references is incorporated herein by reference. The Examiner concludes that the skilled artisan would have found it obvious to use the known processes for oxidizing carbohydrates, including dextrans, and that carbohydrates and oxidized dextrans are also known for delivering iron to subjects in need thereof.

As noted above, claim 11 has been canceled, and HCAPLUS 2 is no longer available as prior art. Further, the cited copending application (11/815,568) was filed in the United States only on August 6, 2007 and has an earliest effective filing date (February 9, 2005), well (nearly 2.5 years) after the earliest effective filing date of the instant application, which is October 23, 2002. Hence it is believed that a non-statutory obviousness-type double patenting is improper in the instant application.

CONCLUSION

Based on the foregoing, the Applicants respectfully request entry of the instant amendment and a Notice of Allowability for claims 1-8 and 12-21. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application. If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, our Order No. GIL-15940.

Respectfully submitted,

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